

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/014935

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl⁷ C07K16/00, A61K9/08, 39/395, 47/02, 47/18, 47/26, A61P35/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl⁷ C07K16/00, A61K9/08, 39/395, 47/02, 47/18, 47/26, A61P35/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MEDLINE (SNT), BIOSIS (STN), WPIDS (STN), JICST FILE (JOIS)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	JP 2001-504092 A (Rotkreuzstiftung Zentrallaboratorium Blutspendedienst SRK), 27 March, 2001 (27.03.01), Claims; examples & EP 835880 A1 & WO 98/16558 A1 & US 6136312 A1	1-4, 9 10, 11
X A	JP 9-127114 A (Dainabot Co., Ltd.), 16 May, 1997 (16.05.97), Claims; example 1; Fig. 1 (Family: none)	1-3, 9, 10 4, 11
X A	JP 9-127112 A (Dainabot Co., Ltd.), 16 May, 1997 (16.05.97), Claims; example 1; Fig. 1 (Family: none)	1-3, 9-11 4

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
04 January, 2005 (04.01.05)Date of mailing of the international search report
25 January, 2005 (25.01.05)Name and mailing address of the ISA/
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	JP 2-786335 A (Biotest Wolfram), 19 March, 1990 (19.03.90), Claims; page 3, upper left column; examples & EP 352500 A & US 5190752 A	1-4, 9 10, 11
X A	JP 2-493 A (Miles Inc.), 05 January, 1990 (05.01.90), Claims; examples; page 5, upper right column & EP 303088 A & US 5157113 A	1-4, 9, 10 11
X	GOMBOTZ WR et al., "The stabilization of a human IgM monoclonal antibody with poly (vinylpyrrolidone)." Pharm Res., 1994, Vol.11, No.5, page 624-32	1-4, 9-11
A	DRABER P. et al., "Stability of monoclonal IgM antibodies freeze-dried in the presence of trehalose." J Immunol Methods., 1995, Vol.181, No.1, pages 37 to 43	1-4, 9-11

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PCT/JP2004/014935**Box No. II** Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
The matter common to claims 1 to 35 is the stabilization of an IgM solution of a high concentration.

The search has revealed that the document (JP 2001-504092 A (Rotkreuzstiftung Zentrallaboratorium Blutspendedienst SRK) 27 March, 2001 (27.03.01)) describes a stabilized IgM solution of a high concentration, and thus, it has become clear that the above common matter is disclosed in said document and therefore is not novel. As a result, the stabilization of an IgM solution of a high concentration falls within the scope of the prior art, and therefore, the common matter cannot be a special technical feature. Accordingly, the inventions according to claims 1 to 35 (continued to extra sheet)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Claims 1 to 4 and 9 to 11

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

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Continuation of Box No. III of continuation of first sheet (2)

are classified into a group of inventions according to claims 1 to 4 and 9 to 11 relating to a solution containing a stabilized immunoglobulin at a high concentration, wherein the immunoglobulin is IgM, a group of inventions according to claims 5 to 8, 13 to 22, 24 to 34 having a technical feature of a high concentration IgM solution containing a multi-valent cationic ion, and a group of inventions according to claims 12, 23 and 35 having a technical feature of the freezing or freeze-drying of a stabilized IgM solution of a high concentration.